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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,494	11/02/2001	Yung-Fu Chang	1258-006 CIP	9399

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,494	CHANG, YUNG-FU	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-50 and 66-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-50 and 66-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/2/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed November 2, 2001is a continuation in part of 09/358,322, filed July 21, 1999, now abandoned.

Applicant's amendment filed April 14, 2006, has been received and entered. It is noted that the after final amendment was not entered, and that formally, that the claims should have the editor marks for the amendments requested on December 19, 2005.

Applicant's arguments provided in the after final received December 19, 2005 are being considered.

Claims 1-46, 51-65 have been canceled. Claims 47, 48 and 50 have been amended. Claims 66-68 have been added. Claims 47-50, 66-68 are pending.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on November 3, 2004, was acknowledged.

No new arguments have been provided and it is noted that claims of some of the non-elected inventions have been canceled. The restriction requirement is maintained for the reasons of record. The requirement is still deemed proper and is maintained as FINAL.

Newly added claims 66-68 are dependent on claims previously examined, and are encompassed by the elected invention.

Claims 47-50, 66-68 are pending and currently under examination to the elected invention of DNA vaccines and methods of making.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application.

In this case, upon review of the specification a protein sequence on page 15 has been identified. Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Objections

Claim 47 is objected to because of the following informalities:

The preamble recites "A recombinant DNA comprising said DNA" and while there is literal support for the antecedent basis of "said" DNA it appears to be circular. It is suggested that the claim be amended to recite "comprising a DNA selected from the group..."

Appropriate correction is required.

Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 49 simply sets forth that "at least one immunogenic epitope" is encoded however this appears to be an inherent and non-limiting property of the sequences encompassed by claim 47 since the sequence must elicit an immune response. There does not appear to be a limitation in claim 47 that is not comprised within claim 49.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims previously objected to under 37 CFR 1.75 as being a substantial duplicates is withdrawn.

Cancellation of the claims has obviated the objection.

Claims 50 and 68 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 48 and 67. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In this case, a close review of the two sets of claims it appears that the claims are duplicates of each other both comprising a vector capable of expressing several specific SEQ ID NOs.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

The cancellation of the claims subject to the rejection has obviated the basis of the rejection.

As noted previously, with respect to the product claims, the only requirement is for a recombinant DNA to be made, and effectively most proteins provide when expressed can be

immunogenic. Since most protein sequences are immunogenic in some context, the rejection over product claims would not be appropriate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-50, 66-68 are rejected under 35 U.S.C. 102(b) as being anticipate by Lewis *et al.* (1994).

Applicant notes the amendments to the independent claims and argue that the teaching of Lewis *et al.* fail to teach the use of the disclosed sequences for use in inducing an immune response to *E. canis*, nor does an inherent ability of the sequences necessarily flow from the teachings of Lewis *et al.* and fail to teach a "recombinant DNA" wherein the sequence elicits an immune response to *E. canis*. Applicants point to the declaration previously filed and note that post-filing experiments demonstrate that the disclosed sequences do induce an immune response when delivered as a DNA vaccine and provides the basis for immunogenic sequences. See pages 11-14, section b of Applicant's amendment. Applicant's arguments have been fully considered, but not found persuasive.

Again it is noted that Applicant does not argue the sequence of Lewis *et al.* does not share homology with the claimed sequences, only that it is not recombinant and that it will not induce an immune response to *E. canis*. Examiner acknowledges that the encoded protein

sequences can be expressed and that they may be able to induce an immune response, however there is no clear teaching of what sequences are immunogenic. The teaching in the specification for identifying potential immunogenic portions of a protein is also acknowledged, however this is general guidance recognized in the art for identifying potential sequences applied to the specific sequences disclosed, and fails to include or exclude any specific sequence from being immunogenic. Given the guidance of the present specification and even the post-filing art there is no evidence to what portions of the disclosed sequences must be present to uniquely elicit an immune response to *E. canis*, therefore the Office is left to interpret the claims from a structural basis. Examiner would agree that Lewis *et al.* does not disclose the use of the sequences to induce an immune response to *E. canis*, however based on the homology and the ability of effectively any sequence to be immunogenic a reasonable interpretation from a structural point of view would be that homologous sequences capable of being immunogenic should meet the limitations of the instant claims. Examiner's reliance on inherency has been established in technical reasoning given the breadth of the claims directed to a product and the structural similarities of the claimed product and that disclosed in the prior art to anticipate structurally the embodiments of the instant claims.

The instant rejection has been made and maintained in light of the breadth of the claims in light of the guidance of the instant specification. With respect to the term recombinant, this is broad general term recognized in the art, and the cloning of the sequences out of the genome and their characterization as disclosed by Lewis *et al.* would constitute a recombinant sequence since it is out of the endogenous content. Further, it is noted that the sequence is manipulated as a DNA molecule. The instant specification does not point to any specific sequence be necessary

nor required for eliciting an immune response, nor do Applicant's arguments differentiate the breadth of the claimed sequences from that of Lewis *et al.* The claims broadly encompass any polynucleotide sequence which encodes an amino acid sequence that can elicit an immune response and vectors capable of expressing said protein. As suggested by Applicant, the rejection relies in part on inherency of the sequence, and given that sequences share structural similarity as demonstrated by their homology, and given the guidance of the instant specification, it is maintained that the sequence specifically disclosed shares stretches of homology that would encode some portion of a protein set forth in SEQ ID NO: 3, 5, 7 and 11. Lewis *et al.* teach the use of expression vectors to screen for inserts, therefore the proteins encoded by the sequences inserted in the vectors of the isolated clones serve a sequence capable of producing a protein that could serve and are capable of producing an immune response.

Conclusion

No claim is allowed. As noted previously, the complete sequence of each of the SEQ ID NOs appear to be free of the prior art of record because the prior art of record fails to teach or suggest the complete polynucleotide sequences or a method of creating a vaccine with said sequences. However, the breadth of the claims encompass any portion or immunogenic fragment of these sequences.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach